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Guidance for the Reregistration of Pesticide Products Containing Ethion as the Active Ingredient

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GUIDANCE FOR THE
REREGISTRATION OF PESTICIDE PRODUCTS
CONTAINING AS THE ACTIVE INGREDIENT

ETHION
(058401)

CASE NUMBER 427

CAS 563-12-2

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D. C. 20460

December 1982

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I. INTRODUCTION

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Each registrant of a currently registered product who wishes to continue to sell or distribute that product in commerce must apply for reregistration.

This guidance document sets forth the requirements for registration and reregistration of all manufacturing-use products (MUPs) containing the subject chemical as the sole active ingredient. These requirements are: that certain scientific data be submitted; that certain standards of toxicity, composition, labeling, and packaging be met; and that the data compensation provisions of FIFRA Section 3(c)(1)(D) be satisfied. Registrants of MUPs are referred to all Sections and Tables for specific information regarding their responsibilities under this guidance document.

This guidance document also sets forth the data requirements and compensation responsibilities for those end-use products which contains the subject active ingredient and for which the source of that active ingredient is (1) not registered with EPA or (2) produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm, or (3) both (1) and (2). Registrants of such end-use products can exempt themselves from these requirements if they change their source of supply to a registered source, provided the source (i.e., registered active ingredient product) is obtained from a firm that does not share ownership in common with the registrant's firm. (If the end-use product registrant decides to switch sources, a new confidential statement of formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this guidance document.) Registrants of affected end-use products are referred to only Sections II, III, IV and VII and Table A for specific information regarding their responsibilities under this guidance document.

It should be noted that end-use products containing the subject active ingredient will not be reregistered at this time. Any necessary labeling changes will be implemented under the Agency's Label Improvement Program at a future time.

EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if the registrant fails to comply with the requirements set forth in this guidance document.

This guidance document has been prepared to provide registrants with specific information on how they may reregister their manufacturing-use products or maintain their end-use product's registration. (Refer to the cover letter's attachment for a listing of your affected products.) If for any reason you decide to request that the Agency discontinue the registration of any of your products subject to the registration requirements in this document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the time frames outlined.

Registrants are reminded that Section 6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

II. REGULATORY POSITION AND RATIONALE

A. INTRODUCTION

This Registration Standard describes the regulatory position of the Environmental Protection Agency (the Agency) on registered manufacturing-use products (MUPs) containing the insecticide and acaricide ethion. The Agency's position is based on an evaluation of all registered uses and registered MUPs with ethion as the sole active ingredient. This position is based on a number of considerations. Foremost among these is an analysis of ethion based on the risk criteria found in Section 162.11a of Title 40 of the U.S. Code of Federal Regulations. The Standard also considers labeling requirements, tolerances, "Special Local Needs" registrations authorized by Section 24(c) of the FIFRA, as well as Federal registrations granted or pending under Section 3 of the FIFRA. Finally, the Agency sets forth the data requirements that must be met to register products covered by this document.

This Standard only addresses registration requirements for current or substantially similar future MUPs and their intermediaries. Ethion MUPs that differ appreciably from those described here may require amendments to the Standard. End-use products (EPs) will be registered under a separate Label Improvement Program.

B. CHEMICAL DESCRIPTION AND USE PROFILE

Ethion is the common name for O,O,O',O'-tetraethyl S,S'- methylene bisphosphorodithioate (ANSI, 1972). Other names include "Nialate" and "Vegfru Fosmite." The Chemical Abstracts Service (CAS) number is 563-12-2 and the EPA Shaughnessy number is 058401. Ethion is an organosphosphorous compound used to control a broad spectrum of insects and mites on many different use-sites. Its principal uses are to control scale and mite pests on Florida citrus. Other use-sites include various fruits, vegetables, ornamentals and turf.

Technical grade ethion is amber with a slight mercaptan odor and a melting point of -12 to -15C. It has a very low vapor pressure at room temperature and is practically insoluble in water (2 ppm), but miscible with nonpolar organic solvents. The compound will hydrolyze in acidic or basic media, and will oxidize slowly in air.

As of September 1, 1982, there are three Federally registered MUPs: FMC Corporation's "Ethion Technical Insecticide" (279-2280), Tricon Chemicals International's "Ethion Technical" (44600-2), and Aceto Chemical's "Ethion Technical Insecticide" (2749-293: voluntarily suspended; no data are available for review on this product). The FMC and Aceto products contain 95% ethion, and the Tricon product is 94% ethion. There are 43 Federally registered end-use products containing ethion as their sole active ingredient, 27 other products formulated with oil, and 17 which contain ethion plus other active ingredients. In addition there are a number of intrastate and "Special Local Needs" registrations.

Formulations include dusts (1% and 4%), granules (1.15% to 10.0%), wettable powders (25%), and emulsifiable concentrates (1, 4, and 8 lb/gal; 3% to 18.6%). Emulsifiable concentrates and wettable powders are applied to foliage by aerial or ground application (including airblast sprayers). Granular formulations are applied in furrows at planting, while dust formulations have little if any use on commercial agricultural crops. Applicators need not be certified to apply ethion.

C. REGULATORY POSITION

Based on a review and evaluation of all available data and other relevant information on ethion, the Agency has made the following determinations:

1. Manufacturing-use pesticide products containing ethion as a sole active ingredient may be registered for sale, distribution, reformulation, and use, subject to the terms and conditions specified in this Standard.

2. Available data do not show that any of the criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of ethion specified in this Standard. However, gaps in the data base preclude the completion of the Agency's risk assessment.

3. Registrants must provide or agree to develop additional data, as specified in the tables attached to this Standard, in order to maintain existing registrations or to permit new ethion registrations.

4. Tolerance reassessment is normally a part of a Registration Standard review. The Agency is unable to complete its reassessment of this compound, though, because essential residue and plant and animal metabolism tests are not available. These gaps are of considerable concern because the Theoretical Maximum Residue Contribution (TMRC) is 2 1/2 times greater than the Maximum Permissible Daily Intake (MPI).

D. REGULATORY RATIONALE

The Agency has determined that it should continue to allow the registration of ethion after considering the following:

1. Data on acute oral testing is sufficient to assign an LD_{50} in rats of 24.4 mg/kg (MRID 00034384). The toxicological symptoms reported were typical of cholinesterase inhibition. Adequate studies were also available to assess acute dermal irritation and subchronic oral toxicity. Requirements for chronic feeding studies and mutagenicity have been partially met, but data in other toxicological areas are missing. From the available information, no toxicological hazards of concern have been identified that cannot be mitigated by product labeling.

2. Even though the TMRC currently exceeds the MPI, no existing evidence suggests that current tolerances are likely to result in residue levels that will expose the public to unreasonable adverse effects.

3. Available data are insufficient to fully assess the environmental fate of ethion. Several studies suggest that ethion is not expected to move into water supplies, and does not persist long in the environment. Aquatic monitoring studies rarely show evidence of ethion either in water or sampled organisms, while in soil ethion has a reported half-life of less than two months. However, additional data in photodegradation, hydrolysis, and dissipation are needed to confirm these expectations.

4. From available wildlife studies, Agency scientists are able to assess the toxicity of ethion to several terrestrial and aquatic test organisms. Ethion is practically non-toxic to mallard ducks and bobwhite quail in subacute doses, however avian acute toxicity has not been determined. Ethion is highly toxic to freshwater fish and very highly toxic to freshwater invertebrates and mature shrimp. Studies of toxic effects on beneficial insects report somewhat variable results, although ethion appears to be at least moderately toxic to many beneficial insects, including honeybees. Label warnings required by this Standard should protect fish and other wildlife from known hazards. However, since ethion use patterns on corn, cotton, and citrus involve applications near estuarine systems, its acute toxicity to juvenile estuarine organisms must be ascertained so the hazard to aquatic species can be clarified.

5. Available data on both human and wildlife poisoning incidents indicate that the majority of cases cited in the Pesticide Incident Monitoring System through February of 1982 appeared to be the result of misuse or accident. However, due to inadequate information on the possible hazards presented to agricultural workers in orchards or fields treated with ethion, the Agency requires that MUP registrants propose reentry intervals for each treated crop (see Chart A-2, "Environmental Fate," for further details). Presently a crop reentry interval of 24 hours for ethion is set forth in 40 CFR Part 170, however, most current EUP labels do not list any reentry intervals. The Agency's Farm Safety Label Improvement Program will soon require the listing of the 24-hour interval on labels of ethion EUPs used on crops employing hand labor operations. The 24-hour reentry interval should be considered an interim measure until more thoroughly documented intervals are proposed and implemented.

6. It is not the Agency's policy to cancel or withhold registration because data are missing or inadequate (see Sections 3(c)(2)(B) and 3(c)(7) of the FIFRA). Rather, publication of this Standard provides a mechanism for identifying data needs; and registration under the Standard allows for the upgrading of labels during the period in which the required data are being developed. These data will be reviewed and evaluated when they are received and the Agency will determine at that time whether they will affect the registration(s) of ethion.

E. CRITERIA FOR REGISTRATION UNDER THIS STANDARD

To be covered by this Standard, manufacturing-use products must: contain ethion as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of MUPs subject to this Standard must comply with all terms and conditions described in it. That includes making a commitment to fill data gaps on a schedule specified by the Agency. Applicants must also indicate a willingness to pay compensation for data to the extent required by Section 3(c)(1)(D) of the FIFRA, as amended, 7 U.S.C. 136 (c)(1)(D). Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

F. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be covered under this Standard, manufacturing-use products must contain at least 94% ethion as the sole active ingredient. Each MUP formulation proposed for registration must be fully described with an appropriate certification of limits.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade products and MUPs containing ethion for any acute toxicity category, provided that the labeling of those products bear appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard, MUPs containing ethion may be labeled for formulation only into end-use products for outdoor use on:

almonds
apples
apricots
beans (dry & succulent)
blueberries
cherries
chestnuts
corn (fields)
cotton
cucumbers
domestic buildings
outdoors (for clover mites only; use limited to professional pest control operators)
eggplants
filberts
garlic
grapefruit
grapes
leeks
lemons
limes
melons
nectarines
onions
ornamentals
oranges
peaches
pears
pecans
peppers
pimentos
plums
prunes
sorghum (grain or forage)
summer squash
strawberries
tangelos
tangerines
tomatoes
turf
walnuts

or for greenhouse use on:

ornamentals.

End-use products formulated from products registered under this Standard may be dusts, granules, wettable powders, or emulsifiable concentrates.

G. Required Labeling

All technical grade, manufacturing-use, and end-use products containing ethion must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements.

1. Use Pattern Statements

The ingredient statement for MUPs will list the active ingredient as: "O,O,O',O'-tetraethyl S,S'-methylene bisphosphorodithioate _____%. In addition, all MUPs must contain the statement, "For formulation into end-use insecticide/miticide products intended only for outdoor use on [crops to be specified]."

2. Precautionary Statements

Labels for all products containing ethion must bear statements reflecting the acute human toxicity of the compound. The guidance package provides an updated list of all precautionary statements which must appear for each type of product. The following environmental hazard warning must appear on manufacturing-use product labels:

> This product is toxic to fish and wildlife. Do not discharge into lakes, streams, ponds, or public waters except in accordance with a NPDES permit. For further guidance contact the nearest EPA Regional Office.

Label changes to EUPs are not required by this Standard; however, based on data reviewed by the Agency, the following environmental statements will be called for when EUPs are reregistered under the Agency's Label Improvement Program. End-use products meant for application to corn, cotton, and/or citrus will contain the following statement:

> This product is toxic to fish, wildlife, and shrimp. Do not apply directly to water or wetlands. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water by cleaning of equipment or disposal of wastes.

The same statement should be placed on the labels of all other EUPs with the first sentence shortened to read:

> This product is toxic to fish and wildlife.

The labels of all granular formulations may also shorten the third sentence by omitting the words "Drift and...." Granular formulation labels should also contain the statement:

> Cover or incorporate granules that are spilled during loading.

The Agency may impose additional label requirements after review of data to be submitted under this Standard.

H. TOLERANCE REASSESSMENT

A summary of tolerances for ethion including its oxygen analog, S-[[(diethoxy- phosphinothioyl) thio] methyl] O,O-diethyl phosphorothioate, is presented in Table I.

Tolerances for numerous raw agricultural commodities as well as processed products are not supported by available data (see Table II). In addition, data are also required to determine the necessity of food additive tolerances for some processed products.

The Theoretical Maximum Residue Contribution (TMRC) calculated from existing tolerances is 0.7730 mg/day/ 1.5 kg diet. The Acceptable Daily Intake (ADI) based on the NOEL from a human cholinesterase study (MRID 00073157) is 0.005 mg/kg/day. When multiplied by a bodyweight of 60 kg, this gives a Maximum Permissible Daily Intake (MPI) of 0.30 mg/day. Thus the TMRC is 258% of the ADI.

Little is known of the metabolism of ethion in animals and plants. It is known that residues in or on ethion-treated fruit consist of ethion, ethion monooxon, and ethion dioxon, but nothing is known of the uptake and distribution of ethion or whether the above products are formed as a result of metabolism or physical/chemical degradation. In radiolabeled ethion-dosed dairy cattle, uncharacterized radioactivity is distributed throughout all tissues and milk within the 28-day dosing period; about 77% of the radioactivity is lost from tissues following a 12-day recovery period (MRID 00073144). No information was available about rates and routes of elimination or the identity and relative levels of metabolities associated with the metabolism of ethion in food animals. Thus, there are data gaps for both plant and animal metabolism.

The Agency will reassess all ethion tolerances when the necessary residue and metabolism studies are received. The Agency will address whether ethion tolerances should continue to be expressed in terms of combined levels of ethion and ethion monooxon or should also include ethion dioxon when adequate plant and animal metabolism studies are available.

Table I. Summary of present tolerances

Commodity	Tolerances (ppm) United States	Canada	Mexico	International (Codex)
Almonds	0.1	0.1[a]	--	0.1[a]
Almond hulls	5	--	--	--
Apples	2	2	2	2
Apricots	0.1	--	--	0.1[a]
Beans	2	1	2	2
Cattle, fat	2.5	2.5	--	2.5
Cattle, meat, and meat by-products	0.75	2.5	--	0.75
Cherries	0.1	--	--	0.1[a]
Chestnuts	0.1	--	--	0.1[a]
Citrus fruits	2	2	1[b]	2
Citrus pulp, dried	10[c]	--	--	--
Corn, fodder and forage	14	--	14	--
Corn, grain	0.1[a]	--	0.1[a]	0.05[a]
Cottonseed	0.5	--	0.5	0.5
Cucumbers	0.5	0.1[a]	0.5	0.5
Eggplants	1	0.1[a]	1	1
Eggs	0.2	--	--	0.2[a]
Filberts	0.1	--	--	0.1[a]
Garlic	---	--	--	1
Goats, fat, meat, and meat by-products	0.2	--	--	0.2
Grapes	2	2	1	2
Hogs, fat, meat, and meat by-products	0.2	--	--	0.2[a]
Horses, fat, meat, and meat by-products	0.2	--	--	0.2[a]
Melons	2	0.1[a]	2	2
Milk fat	0.5[a]	--	--	0.5[a]
Nectarines	1	--	--	1
Onions	1	0.1[a]	1	1
Peaches	1	1	1	1
Pears	1	2	1	2
Pecans	0.1	--	0.1	0.1[a]
Peppers	1	0.1[a]	1[d]	1
Pimentos	1	0.1[a]	--	1
Plums, prumes (fresh)	2	1	--	2
Poultry, fat, meat, and meat by-product	0.2	--	--	0.2[a]
Raisins	4[c]	--	--	--

[a]Negligible residue level basis.
[b]Mandarin oranges only.
[c]Food additive tolerance.
[d]Chili peppers only.
[e]Summer squash only.

Table I. Summary of present tolerances (Cont'd)

Commodity	Tolerances (ppm)			
	United States	Canada	Mexico	International (Codex)
Sheep, fat, meat, and meat by products	0.2	--	--	0.2[a]
Sorghum, forage	2	--	--	--
Sorghum, grain	2	--	1	--
Strawberries	2	1	2	2
Squash	0.5[e]	0.1[a]	0.5	0.5
Tea, dried	10[c]	--	--	5
Tomatoes	2	0.5	2	2
Walnuts	0.1	--	--	0.1[a]

[a]Negligible residue level basis.
[b]Mandarin oranges only.
[c]Food additive tolerance.
[d]Chili peppers only.
[e]Summer squash only.

III. DATA COMPENSATION

As part of your application for reregistration, you must comply with the data requirements of FIFRA Section 3(c)(1)(D) by including with your application a completed Data Compensation Statement (Appendix III-1). That form includes:

A. A statement that you offer to pay compensation to other persons with regard to the application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D).

B. A statement acknowledging that if EPA approves your application for registration, the approval will be based on EPA's consideration of the following:

1. All the existing "generic" data* which, according to the table, "Generic Data Requirements for Manufacturing-Use and End-Use Products" (Table A at the end of Section IV), is relevant to EPA's evaluation of the registrability of your product.

2. For the manufacturing-use products, the "product-specific" data** which you have listed on the form entitled "Product-Specific Data Report" (Appendix III-2).

C. A statement that you have furnished an offer to pay compensation to the person(s) listed below in the manner specified:

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*/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

**/ Product-specific data pertain to data that support the formulation which is marketed; such data usually include product chemistry data and acute toxicology data.

1. Persons to whom offers must be made: An offer must be furnished to each person who was the original submitter of any of the generic or product-specific data upon which approval of your application will be based, except that:

   a. You need not furnish an offer with respect to data that were originally submitted prior to January 1, 1970.

   b. Many data submitters have informed EPA that they do not wish to receive offers under FIFRA Section 3(c)(1)(D). The various persons who submitted data listed in the bibliography (Appendix III-3) who have not waived their rights to receive offers will be listed in Tables A and B (MUP registrants are referred to in both Tables A & B; end-use product registrants are referred to only in Table A). You will be required to write the companies listed in the appropriate table(s) if the data in those tables are required to support your formulations and/or uses.

   c. You need not furnish an offer to any person with whom you have already agreed in writing concerning the amount (if any) and terms of compensation payable under FIFRA Section 3(c)(1)(D) in connection with the reregistration of your product.

   d. You need not furnish an offer with respect to any data unless the data were submitted to EPA (or its predecessor agencies) to support an application for registration, amended registration, or reregistration; to support or maintain in effect an existing registration; to support an application for an experimental use permit; or to support a petition for a tolerance, food additive regulation, or other clearance under the Federal Food, Drug and Cosmetic Act which was a prerequisite to a FIFRA registration action.

2. Form of the offer: You must furnish each person who is entitled to receive an offer the following information, in writing:

   a. A notification of your intent to apply for registration or reregistration under this guidance document, and the name, active ingredient, and intended uses of your product.

b. An offer to pay the person compensation with respect to approval of your application to the extent required by FIFRA Sections 3(c)(1)(D) and 3(c)(2)(D), and an offer to begin negotiations to set the amount and terms of compensation.

c. Your name, mailing address, and telephone number.

IV. REQUIREMENT FOR SUBMISSION OF GENERIC DATA UNDER FIFRA SECTION 3(c)(2)(B)

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B). EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this section. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA approved protocols, The Pesticide Registration Guidelines,* or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

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*/ The Pesticide Registration Guidelines were reproposed on November 24, 1982, in 47 Federal Register 53192.

Also, for certain kinds of testing (generally Ecological Effects), EPA requires the test substance to be a "typical formulation," and that in those cases EPA needs data of that type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.). These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Section V of this document.

C. Options Available for Complying with Requirements to Submit Data.

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA § 3(c)(2)(B) Summary Sheet" [Appendix IV-2(a)] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" (Appendix IV-3*.)

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement between all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section (3)(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)], and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted.

If the test procedures you plan to use deviate from (or are not specified in) registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

V. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA UNDER FIFRA § 3(c)(2)(B)

Note: This section applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B) EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than 6 months after you receive this guidance document.

CHART A-1

Generic Data Requirements for Ethion: PRODUCT CHEMISTRY

Guidelines Citation §158.24	Name of Test	Composition	Does EPA have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? **
61-1	Product Identity and Disclosure of Ingredients	Technical Grade (TGAI)	Partially[3]/	00073070, 00073169*	Yes[1]/
61-2	Description of Manufacturing Process	TGAI	Partially[4]/	00073057, 00073070	Yes[1]/
61-3	Discussion of Formation of Unint. Ingredients	TGAI	Partially[3]/	00073070, 00073169*	Yes[1]/
62-1 and 62-2	Declaration and Certification of Ingredient Limits	TGAI	Partially[5]/	00073070, 00073169*	Yes[1]/
62-3	Product Analytical Methods and Data	TGAI	Partially[6]/	00073057, 00073070[2]/	Yes
63-2	Color	TGAI	Yes	00073070, 00073169*	No
63-3	Physical State	TGAI	Yes	00073070, 00073169*	No
63-4	Odor	TGAI	Yes	00073070, 00073169	No

1/ These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. References cited are applicable only to the currently registered technical products, 279-2280 and 44600-2.
2/ Other citations include: Launer, 1969, JAOAC 62(1):11-14; Ethion EPA-1 and Ethion EPA-2 (Tentative) in EPA, 1974, Manual of Chemical Methods for Pesticides and Devices.
3/ The identity of impurities was not conclusively determined in product 279-2280. No data were available for 44600-2.
4/ The composition of starting materials, details of the equipment used, and reaction conditions were not provided.
5/ An update of the methods used for quality control of 279-2280 is required. No data were available for 44600-2.
6/ The methods presented require validation and sensitivity data.

CHART A-1

Generic Data Requirements for Ethion: PRODUCT CHEMISTRY

Guidelines Citation § 158.24	Name of Test	Composition	Does EPA have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? **
63-5	Melting Point	TGAI	Yes	00073070, 00073169*	No
63-6	Boiling Point	TGAI	No		Yes
63-7	Density or Specific Gravity	TGAI	Yes	00073070, 00073169*	No
63-8	Solubility	TGAI	Yes	00073070, 00073169*	No
63-9	Vapor Pressure	TGAI	Yes	00073070, 00073169*	No
63-10	Octanol/Water	TGAI	No		Yes
63-13	Stability	TGAI	Yes	00073070, 00073169*	No

* Studies submitted by FMC. These studies may be compensable.
** All data must be submitted within 6 months (due June 30, 1983).

CHART A-2

Generic Data Requirements for Ethion: ENVIRONMENTAL FATE

Guidelines Citation §158.26	Name of Test	Use Pattern*	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?
161-1	Hydrolysis	A,B,E,H	Radiolabeled analytical grade or non-labeled TG	No		Yes
161-2	Photodegradation in Water	A,B	-SAME-	No		Yes
161-3	Photodegradation in Soil	A,B	-SAME-	No		Yes
162-1	Aerobic Soil Metabolism	A,B,E,H	-SAME-	Partially[1]/	00073059, 00043982	Yes
162-2	Anaerobic Soil Metabolism	A	-SAME-	No		Yes
Reserved	Effects of Microorganisms		-SAME-	No		RESERVED[2]/
Reserved	Activated Sludge Metabolism		-SAME-	No		RESERVED[2]/
163-1	Leaching	A,B	-SAME-	No		Yes
163-2	Laboratory Volatility	A,E	Technical Grade	Yes	05015434	No

* Use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food, E= Greenhouse Use; H= Domestic Outdoor.

CHART A-2

Generic Data Requirements for Ethion: ENVIRONMENTAL FATE

Guidelines Citation §158.26	Name of Test	Use Pattern*	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?
164-1	Field Dissipation-Terrestrial	A,B,H	Typical end-use product of major formulation category	Partially[3]/	05014789, 00073193,* 00073115,* 05020663 00047258, 05004978 00073114,* 05005136 05005044	Yes
164-5	Dissipation-Long Term Studies	A	-SAME-	No		No
165-1	Confined Accumulation Rotational Crops	A	Radiolabeled analytical grade	No		Waived[4]/
165-2	Field Accumulation-Rotational Crops	A	Typical end-use product of major formulation category	No		Waived[4]/
165-4	Fish Accumulation-Laboratory Studies	A,B	Radiolabeled analytical grade or non-labeled TG	No		Yes
Subpart K	Reentry	A	-SAME-	No		Yes[5]/

* Use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-food; H = Domestic, Outdoor.

FOOTNOTES - ENVIRONMENTAL FATE CHART A-2

1/ An additional study is needed to identify and quantify ethion degradation products.

2/ The requirement for these tests is being reserved pending development or modification of testing protocols.

3/ Data are needed on all formulations other than the emulsifiable concentrate.

4/ Waived because use of ethion or rotated crops is minor.

5/ For each crop, the registrant must propose an acceptable reentry interval. This proposed interval may be based on any of the following:

a. The longest (most restrictive) existing reentry intervals (currently those in effect in California- 30-days for citrus, 14 days for peaches, nectarines, and grapes, 2 days for other crops);

b. Data on dissipation of foliar residues (decline curve), on human exposure to those residues, and on the inherent toxicity of the chemical;

c. Determination of that time beyond which there are no detectable foliar residues (under appropriate climatic conditions) in the areas where the chemical will be applied.

Either the longest ((most restrictive) reentry interval is acceptable, or the exposure data and a dislogeable residue curve, together with the inherent toxicity of the chemical, may be used to establish an appropriate interval for activities that result in foliar contact, the longest (most restrictive) reentry interval will be listed by crop.

* Studies submitted by FMC. These studies may be compensable.

** All data must be submitted within 36 months (due December 1985).

CHART A-3

Generic Data Requirements for Ethion: TOXICOLOGY

Guidelines Citation §158.26	Name of Test	Use Pattern* and Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?
81-1	Acute Oral Toxicity	Technical Grade (TG)	Yes	00034384*	No
81-2	Acute Dermal Toxicity	TG	Partially[1]/	00073126	Yes
81-3	Acute Inhalation Toxicity	TG	Partially[2]/	00073126	Yes
81-4	Primary Eye Irritation	TG	Partially[1]/	GS0090-002*	Yes
81-5	Primary Dermal	TG	Yes	00073126	No
81-6	Dermal Sensitization	TG	No		Yes
81-7	Acute Delayed Neurotoxicity	TG	No		Yes
82-1	Subchronic Oral Toxicity	TG	Yes	0073077, 00073150, 00073157*	No
82-2	Subchronic 21-day Dermal Toxicity	TG	No		Yes

All requirements apply to registrations for the following use patterns: Terrestrial, Food Crop (A); Terrestrial, Non-Food (B); Domestic Outdoor (H); Greenhouse Use (E).

1/ The number of animals used is insufficient.

2/ A study is available on the 25% Wettable Powder. Studies are require on each MUP.

CHART A-3

Generic Data Requirements for Ethion: TOXICOLOGY

Guidelines Citation §158.26	Name of Test	Use Pattern and Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?**
82-3	Subchronic 90-day Dermal Toxicity	TG	No		No[3]/
82-4	Subchronic Inhalation Toxicity	TG	No		Reserved[4]/
82-5	Subchronic Neurotoxicity	TG	No		Reserved[5]/
83-1	Chronic Feeding	TG	[6]/	GS0090-003*	Yes[7]/
83-2	Oncogenicity	TG	No		Yes[7]/
83-3	Teratogenicity	TG	No		Yes[7]/
83-4	Reproduction	TG	No		Yes[7]/
84-2 through -4	Mutagenicity	TG	Partially[8]/	GS0090-004 *	Yes[7]/
85-1	Metabolism (Identification of Metabolites)	Radiolabeled, Analytically Pure Grade of A.I.	No		Yes

FOOTNOTES -- TOXICOLOGY CHART A-3

3/ No study is required since the pesticidal uses of ethion exclude swimming pools and fabrics and do not involve intentional application to the skin.

4/ This study may be necessary pending the outcome of the acute inhalation study (163.81).

5/ This study may be necessary pending the outcome of the acute delayed neurotoxicity study (163.81-7).

6/ A 24-month feeding study with dogs (GS0090-003) may be acceptable pending reevaluation by the Agency. A study on rodents is required.

7/ According to the FMC Corporation these studies will be completed as follows:

Study	Estimated Completed Date
chronic/oncogenic, rat	June 1985
chronic/oncogenic, mouse	June 1985
reproduction, rat	June 1985
teratology, rat	August 1983
teratology, rabbit	August 1983

8/ A dominant lethal asasy in mice showed no effect in number of implantation resorptions and embryos. The following studies represent the minimum additional data likely to be required on the potential heritable effects of ethion:

a. A mammalian in vitro point mutation test.
b. A sensitive submammalian point mutation test (bacteria, fungi, insect).
c. A primary DNA damage test (i.e., sister chromatid exchange or unscheduled DNA sysnthesis).
d. A mammalian in vitro cytogenics test. If this suggests a positive result, a dominant lethal or heritable translocation test may be required.

After results from these tests and other toxicology disciplines have been considered, additional testing may be required to characterize or quantify the potential genetic risks.
Although the Agency mutagenic testing requirements are not final, the standards for these tests should be based on the principles set forth in FR 43, No. 163 (August 22, 1978).

* Studies submitted by FMC. These studies may be compensable.

** All data must be submitted within 36 months (due December 1985) except 81-2, 81-3, 81-4, 81-6, and 81-7 which are due June 30, 1983.

CHART A-4

Generic Data Requirements for Ethion: RESIDUE CHEMISTRY

Guidelines Citation §158.24	Name of Test	Composition	Does EPA have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?
—	Metabolism in Plants	Radiolabeled Technical Grade Active Ingredient	No		Yes
—	Metabolism in Animals	-SAME-	Partially[1]/	00073144	Yes
—	Analytical Methods	Representative Formulation	Partially[2]/	00073812, 00073147, 00073141 00073811, 00073143, 00073100 00073173*	Yes
—	Residue Data, Crops	-SAME-			
	Onions	-SAME-	Yes	00073121, 00073152 00073085	No
	Beans	-SAME-	Partially[3]/	00073085, 00073152	Yes
	Eggplants	-SAME-	Partially[3]/	00073095	Yes
	Peppers	-SAME-	Partially[3]/	00073189	Yes
	Tomatoes	-SAME-	Partially[3]/	00073133	Yes
	Cucumbers	-SAME-	Partially[3]/	00073806	Yes

1/ The following additional data are required.
a. The rates and routes of elimination of radiolabelled ethion from food animals (including a materials balance);
b. The identification of metabolites formed;
c. The sites of such metabolism;
d. The relative levels of ethion and any metabolites and their distribution in tissues and milk.

CHART A-4

Generic Data Requirements for Ethion: RESIDUE CHEMISTRY

Guidelines Citation §158.24	Name of Test	Composition	Does EPA have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFIRA 3(c)(2)(B)?
	Melons	Representative Formulation	Partially[3]/	00073152	Yes
	Summer Squash	"	No		Yes
	Citrus Fruits	"	Partially[3]/	00073143	Yes
	Apples	"	Partially[3]/	00073808	Yes
	Pears	"	Partially[3]/	00073083, 00073152	Yes
	Apricots	"	Yes	00073806, 00073162	No
	Cherries	"	Yes	00073162	No
	Peaches	"	Partially[3]/	00073082, 00073083	Yes
	Nectarines	"	Partially[3]/	00073195	Yes
	Plums and Fresh Prunes	"	Partially[3]/	00073145, 00073083	Yes
	Grapes and Raisins	"	Partially[3]/	00073808, 00073083	Yes
	Strawberries	"	Partially[3]/	00073152, 00034874	Yes

CHART A-4

Generic Data Requirements for Ethion: RESIDUE CHEMISTRY

Guidelines Citation §158.24	Name of Test	Composition	Does EPA have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?
	Corn (field)	Representative Formulation	Yes	00073173*00073132, 00073 175*	No
	Sorghum	-SAME-	Partially[3]/	00034311	Yes
	Almonds	-SAME-	Partially[3]/	00073095	Yes
	Chestnuts	-SAME-	No		Yes
	Filberts	-SAME-	Partially[3]/	00073162	Yes
	Pecans	-SAME-	No		Yes
	Walnuts	-SAME-	Partially[3]/	00073162	Yes
	Cottonseed	-SAME-	Partially[3]/	00073160, 00073158*	Yes
—	Residue Data: Proposed Commodities	Representative Formulation	Partially[3]/	00073053	Yes
—	Residue Data: Meat, Milk, Poultry and Eggs	-SAME-	Partially[3]/	00073138, 00073153* 00073161	Yes

FOOTNOTES-- RESIDUE CHEMISTRY CHART A-4

2/ Two GC methods appear adequate but require further testing, principally to confirm their validity.

3/ Residues data are required concering ethion and ethion monooxon residues in or on the following raw agricultural commoditie (reflecting the following formulations and/or uses: beans (4% D, maximum rate for 4 or 8 lb/gal EC, ethion monooxon data for 25% WP uses, and aerial application for the 4% D and 4 or 8 lb/gal EC), eggplant (4% D, 25% WP ethion monooxon data for 4 or 8 lb/gal EC uses, and aerial applications of 4 or 8 EC), peppers (4% D, ethion monooxon data for 4 or 8 lb/gal EC and 25% WP uses, and aerial applications of 4% D and 4 or 8 lb/gal EC), pimentos (4% D, 25% WP, 4 or 8 lb/gal EC, and aerial applications of 4% D or 8 lb/gal EC), tomatoes (4% D, 25% WP, 4 or 8 lb/gal EC, and aerial applications of 4% D and 4 or 8 lb/gal EC), cucumbers (aerial applications of 4 or 8 lb/gal EC), melons (4% D, 25% WP, 4 or 8 lb/gal EC, and aerial applications of 4% D and 4 or 8 lb/gal EC), summer squash (25% WP, 4 or 8 lb/gal EC, and aerial applications of 4 or 8 lb/gal EC), citrus fruits (4% D 25% WP, 4 or 8 lb/gal EC, and aerial applications of 4% D), apples (foliar ground applications of 25% WP, and 4 or 8 lb/gal EC, and foliar, aerial applications of 4% D and 4 or 8 lb/gal EC), pears (foliar ground applications of 25% WP and 4 or 8 lb/gal, EC), nectarines (foliar, ground applications of 4% D, 25% WP, 4 or 8 lb/gal EC, and foliar, aerial applications of 4% D and 4 or 8 lb/gal EC), peaches (foliar, ground applications of 4% D, 25% WP, 4 or 8 lb/gal EC, and foliar, aerial applications of 4% D and 4 or 8 lb/gal EC, plums/fresh prunes (foliar, ground applications of 4% D 25% WP, and 8 lb/gal EC and foliar, aerial applications of 4% D and 8 lb/gal EC), grapes (two 4% D treatments at 1.2 lb ai/A 25% WP, 4 or 8 lb/gal EC, and aerial applications of 4% D and 4 or 8 lb/gal EC), strawberries (three or more seasonal treatments of 4% D with a 2-day PHI, maximum rate of 25% WP, maximum rate of 8 lb/gal EC or three or more seasonal applications of 4 lb/gal EC, and aerial applications of 4% D and 4 or 8 lb/gal EC), field corn (ethion monooxon residues in or on grain and fodder following aerial and ground use of 4% D and 4 or 8 lb/gal EC), sorghum (three ground treatments of 25% WP and 4 or 8 lb/gal EC and three aerial treatments with 4 or 8 lb/gal EC), almonds (hulls treated with foliar, ground applications of 25% WP and meats and hulls treated with foliar aerial and ground applications of 4% D and 8 lb/gal EC), chestnuts (25% WP, 4 or 8 lb/gal EC, and aerial applications of 4 or 8 lb/gal EC), filberts (25% WP, 4 or 8 lb/gal EC, and aerial applications of 4 or 8 lb/gal EC), peacans (25% WP 4 or 8 lb/gal EC, and aerial applications of 4 or 8 lb/gal EC), walnuts (ethion monooxon residue for foliar uses of 25% WP and aerial and ground (foliar) applications of 8 lb/gal EC), and cottonseed (aerial and ground applications of 4% D, 25% WP and 4 or 8 lb/gal EC).

4/ Residue data concerning ethion and ethion monooxon are required to support the food additive tolerances for dehydrated citrus pulp, dried tea leaves, and raisins. Additionally, data are required to determine the necessity of food additive tolerances for: apple products, cottonseed hulls, meat and oil; tomato products; the dried fruit of beans, peppers, and prunes; and dried grape pomace and raisin waste. Fractionation studies on corn and soybeans may also be required if residues are found in the raw agricultural commodities. A feeding restriction for cotton gin trash is required unless the registrant can demonstrate that a food additive tolerance is unnecessary.

5/ Residue data concerning ethion and ethion monooxon are required to support the tolerances for fat, meat, and meat by-products of poultry and to determine if a tolerance for eggs needs to be established.

* Studies submitted by FMC, These studies may be compensable.

** All data must be submitted within 36 months (due December 1985).

CHART A-5

Generic Data Requirements for Ethion: ECOLOGICAL EFFECTS

Guidelines Citation §158.26	Name of Test	Use Pattern* and Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?**
71-1	Avian Single-dose Oral LD_{50}	Technical Grade (TG)	No		Yes
71-2	Avian Dietary LC_{50}	TG	Yes	00022923	No
72-1	Fish Acute LC_{50}	TG	Yes	00003503	No
72-2	Acute Toxicity to Freshwater Aquatic Invertebrates	TG	Yes	00003503	No
72-3	Acute Toxicity to Estuarine and Marine Organisms	TG	No		Yes[1]/
72-4	Fish Embryolarvae and Aquatic Invertebrate Life-Cycle Studies	TG	No		Reserved[2]/
72-5	Fish Life Cycle	TG	No		Reserved[2]/
72-6	Aquatic Organisms Accumulation	TG	No		Reserved[2]/
72-7	Simulated or Actual Field Tests for Aquatic Organisms	TG	No		Reserved[2]/

* All requirements apply to registrations for use on Terrestrial Food Crops (A).

1/ The toxicity of ethion to estuarine organisms must be ascertained because the corn, cotton, and citrus use patterns involve applications very near estuarine systems. It is unlikely that ethion from these applications will reach marine systems in sufficient quantity to produce harmful effects so toxicity tests with marine organisms are not required. The following data on estuarine organisms are required: 1) the 96-hr LC_{50} to juvenile estuarine invertebrates, preferably Penaeus or Palamonetes; 2) the 96-hr LC_{50} for a juvenile estaurine vertebrate, preferably Leiosotom (spot) or Fundulus (killifish); and 3) either a 96-hr oyster shell deposition EC_{50} or a 48-hr oyster embryolarvae EC_{50}, preferably using Crassostrea.

2/ These data may be required if results of Environmental Fate tests indicate that ethion is persistent in water.

** All data must be submitted within 36 months (due December 1985).

CHART B-1

Generic Data Requirements for Ethion: PRODUCT CHEMISTRY

Guidelines Citation §158.24	Name of Test	Composition	Does EPA have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?**
61-1	Product Identity and Disclosure of Ingredients	Each Product	Partially[3]/	00073070, 00073169*	Yes[1]/
61-2	Description of Manufacturing Process	Each Product	Partially[4]/	00073057, 00073070	Yes[1]/
61-3	Discussion of Formation Of Unint. Ingredients	Each Product	Partially[3]/	00073070, 00073169*	Yes[1]/
61-2 and 62-2	Declaration and Certification of Ingredient Limits	Each Product	Partially[5]/	00073070, 000073169*	Yes[1]/
62-3	Product Analytical Methods andd Data	Each Product	Partially[6]/	00073057, 00073070[2]/	Yes
63-2	Color	Each Product	Yes	00073070, 000073169*	No
63-3	Physical State	Each Product	Yes	00073070, 00073169*	No
63-4	Odor	Each Product	Yes	00073070, 00073169*	No

1/ These requirements must be fulfilled by each applicant. Data from other applicants may not be cited. References cited are applicable only to the currently registered technical products, 279-2280 and 44600-2.
2/ Other citations include: Launer, 1969, JAOAC 62(1):11-14; Ethion EPA-1 and Ethion EPA-2 (Tentative) in EPA, 1974, Manual of Chemical Methods for Pesticides and Devices.
3/ The identity of impurities was not conclusively determined in product 279-2280. No data were available for 44600-2.
4/ The composition of starting materials, details of the equipment used, and reaction conditions were not provided.
5/ An update of the methods used for quality control of 279-2280 is required. No data were available for 44600-2.
6/ The methods presented require validation and sensitivity data.

CHART B-1

Generic Data Requirements for Ethion: PRODUCT CHEMISTRY

Guidelines Citation §158.24	Name of Test	Composition	Does EPA have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?**
63-7	Density or Specific Gravity	Each Product	Yes	00073070, 00073169*	No
63-14	Oxidizing/Reducing Action	Each Product	No		Yes
63-15	Flammability	Each Product	Yes	00073070, 00073169*	No
63-16	Explodability	Each Product	Yes	00073070, 00073169*	No
63-17	Storage Stability	Each Product	No		Yes
63-18	Viscosity	Each Product	No		Yes
63-19	Miscibility	Each Product	Yes	00073070, 00073169*	No
63-20	Corrosiveness	Each Product	Yes	00073070, 00073169*	No
63-21	Dielectric Breakdown Voltage	Each Product	No		Yes

* Studies submitted by FMC. These studies may be compensable.

** All data must be submitted within 6 months (due June 30, 1983).

CHART B-2

Generic Data Requirements for Ethion: TOXICOLOGY

Guidelines Citation §158.26	Name of Test	Use Pattern* and Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)?**
81-1	Acute Oral Toxicity	Each Product	Yes	0003438*	No
81-2	Acute Dermal Toxicity	Each Product	Partially 1/	00073126	Yes
81-3	Acute Inhalation Toxicity	Each Product	Partially 2/	GS0090-002*	Yes
81-4	Primary Eye Irritation	Each Product	Partially 1/	00073126	Yes
81-5	Primary Dermal Irritation	Each Product	Yes	00073126	No
81-6	Dermal Sensitization	Each Product	No		Yes

* All requirements apply to registrations for the following use patterns: Terrestrial, Food Crop (A); Terrestrial, Non-Food (B); Greenhouse Use (E); Domestic Outdoor (H).

1/ The number of animals used is insufficient.
2/ A study is available on the 25% Wettable Powder. Studies are required on each MUP.

* Studies submitted by FMC. These studies may be compensable.

** All data must be submitted within 6 months (due June 30, 1983).

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to dermine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under § 3(c)(2)(b)."

In some cases Table B may note that EPA already possesses some or all of the product-specific data needed to evaluate your product; if that is the case, you must comply with FIFRA Section 3(c)(1)(D). See Section III of this guidance document.

VI. LABELING AND PACKAGING INFORMATION

Note: This section applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or re-registration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporate labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you must submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.1], as indicated by the following paragraphs of this section of the guidance document. The labeling must be submitted within 6 months of your receipt of this guidance document.

If owners of currently registered products fail to submit revised labeling and packaging information complying with this section, EPA will issue a notice of intent to cancel the registration under FIFRA § 6(b)(1).

A. Label Contents

40 CFR Section 162.10 (Appendix VI-1) requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix VI-2)

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel,

preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. See Appendix VI-1. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. See Appendix VI-1. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net contents statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. See Appendix VI-1. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No." or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. See Appendix VI-1. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. See Appendix VI-1. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each

active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. See Appendix VI-1. [40 CFR §162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various sized lables, as set forth in the Regulations.

Size of Label on Front Panel in Square Inches	Signal Word As Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" As Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. See Appendix VI-1. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. See Appendix VI-1. [40 CFR §162.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned toxicity Category I on the basis of oral, inhalation or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. See Appendix VI-1. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. See Appendix VI-1. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. See Appendix VI-1 [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. See Appendix VI-1. [40 CFR §162.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particularly hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury, or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to nontarget organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. See Appendix VI-1. [40 CFR §162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability Statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix VI-3. The requirement is based on the results of the flash point determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading

"Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of nonflammability. The following criteria will be used to determine if a product is nonflammable.

   a. A "nonflammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "nonflammable liquid" is one having a flash point greater than 350°F (177°C) as detemined by the method specified in 40 CFR §163.61-8

   c. A "nonflammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)9ii).

      ii. There is no flashback; and

      iii. The flash point of the nonvolatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of nonflammability. Products which meet the criteria for nonflammability specified above may bear the words "nonflammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazard of a physical or chemical nature other than flammability, appropriate statements of hazard

will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." Appendix VI-1. [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE & DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer Appendix VI-5 for the latest specific storage and disposal product labels.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. See Appendix VI-5. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. They should be made part of the response to this notice and submitted for review.

VII. Instruction for Submission

All applications prepared in response to this Notice should be addressed as follows:

William H. Miller
[Phone No. (703) 557-2600]
Registration Division (TS-767)

Office of Pesticide Programs
Environmental Protection Agency
Washington, DC 20460

A. For each manufacturing-use product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section (3)(c)(2)(B) Summary Sheet." Refer to Appendix IV-2(a) with appropriate attachments.

2. Within 6 months from receipt of this document, registrants must submit:

   a. "Application for Amended Pesticide Registration" (EPA Form 8570-1).

   b. "Confidential Statement of Formula" (EPA Form 8570-4).

   c. "Data Compensation Statement: Reregistration." Refer to Appendix III-1(a).

   d. Product Specific Data Report (Appendix III-2).

   e. Two copies of any required product-specific data.

   f. Two copies of draft labeling, including the label and associated brochures. If the current labeling conforms to the requirements of this guidance document and the results of the short-term data, the registrant can submit such labeling. Otherwise, the labeling should be in draft form. The draft labeling should be either typewritten text on 8-1/2 x 11-inch paper or a mock-up of the labeling suitable for storage in 8-1/2 x 11-inch files. The draft label must indicate the intended colors of the final label, clear indication of the front and side panels, and the intended type sizes of the text.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrants.

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission

time will be delayed, notify the Product Manager listed above.

B. For each affected product for which continued registration is desired, within 90 days from receipt of this document submit:

1. The "FIFRA Section 3(c)(2)(B) Summary Sheet" Appendix IV-2) with appropriate attachments, and

2. The "Data Compensation Statement: Reregistration." Refer to Appendix III-1(b).

PRODUCT SPECIFIC DATA REPORT

EPA Registration No. _____

Guidance Document For _____
Date _____

Registration Guideline No.	Name of Test	Test Not Required for My Product Listed Above (Check Below)	I am complying with Data Requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID #	Submitting Data (Attached) (Check Box)	
163.61-3	Product identity and disclosure or ingredients				
163.61-4	Description of manufacturing process				
163.61.5	Discussion of formation of unintentional ingredients				
163.61.6	Declaration and certification of ingredient limits				
163.61.7	Product analytical methods and data				
163.61-8(1)	Color				
163.61-8(2)	Odor				
163.61-8(3)	Melting point				
163.61-8(4)	Solubility				
163.61-8(5)	Stability				
163.61-8(6)	Octanol/water partition coefficient				
163.61-8(7)	Physical state				
163.61-8(8)	Density or specific gravity				
163.61-8(9)	Boiling point				
163.61-8(10)	Vapor pressure				
163.61-8(11)	pH				
163.61-8(12)	Storage stability				
163.61-8(13)	Flammability				
163.61-8(14)	Oxidizing or reducing action				
163.61-8(15)	Explosiveness				
163.61-8(16)	Miscibility				
163.61-8(17)	Viscosity				
163.61-8(18)	Corrosion characteristics				
163.61-8(19)	Dielectric breakdown voltage				

PRODUCT SPECIFIC DATA REPORT

Guidance Document For _____

Date _____

EPA Registration No. _____

Registration Guideline No.	Name of Test	Test Not Required for My Product Listed Above (Check Below)	I am complying with Data Requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID #	Submitting Data (Attached) (Check Box)	
163.71-5(1)	Cage or pen field test				
163.71-5(2)	Full-scale field test				
163.72-1	Fish acute LC_{50} - rainbow trout and bluegill				
163.72-2	Acute toxicity to aquatic invertebrates				
163.72.3	Acute toxicity to estuarine and marine organisms				
163.72-6(a)(1)	Short-term simulated field test				
163.72-6(a)(2)	Long-term simulated field test				
163.81-1	Acute oral toxicity				
163.81-2	Acute dermal toxicity				
163.81-3	Acute inhalation toxicity				
163.81-4	Primary eye irritation				
163.81-5	Primary dermal irritation				
163.81-6	Dermal sensitization				

Appendix III-1(a)

DATA COMPENSATION STATEMENT: REREGISTRATION (MUPs)

EPA Reg. No.: _____

Product Name: _____

Applicant's Name & Address: _____

_____

_____

Date of Application for Reregistration: _____

Registration Standard for Products Containing: _____

Date ReRegistration Guidance Document Issued: _____

In connection with applicant's application for re-registration under the Guidance Document identified above:

(A) Applicant offers to pay compensation to other persons to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended.

(B) Applicant understands and acknowledges that if EPA approves the application, the approval will be based solely on EPA's consideration of:

(1) All the generic data which, according to the Guidance Document identified above, were found relevant to EPA's evaluation of the registrability of applicant's product;

(2) The product-specific data listed on the form entitled "Product-Specific Data Report" which is part of this application; and

(3) Applicant states that offers to pay compensation have been furnished to the persons and in the form specified by the Guidance Document identified above.

Dated: _____

Name of registrant's authorized representative:

_____
(Signature)

_____
(Typed)

Appendix III-1(b)

DATA COMPENSATION STATEMENT: REREGISTRATION (End-Use Products)

EPA Reg. No.: _____

Product Name: _____

Applicant's Name & Address: _____

_____

_____

Date of Application for Reregistration: _____

Registration Standard for Products Containing: _____

Date Reregistration Guidance Document Issued: _____

Registrant offers to pay compensation to other persons for the data listed in Table A to the extent required by sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Registrant has furnished offers to pay compensation to the persons identified in Table A and in the form specified by the Guidance Document.

Dated: _____

Name of registrant's authorized representative:

_____
(Signature)

_____
(Typed)

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources, including the published literature in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID number. This number is unique to the citation and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of materials submitted to EPA, by a description of the earliest known submission. Bibliograhic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission.

   (1) Submission Date. Immediately following the word "received" appears the date of the earliest known submission.

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the

relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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CERTIFICATION OF ATTEMPT TO ENTER
INTO AN AGREEMENT WITH OTHER REGISTRANTS
FOR DEVELOPMENT OF DATA
(TO QUALIFY, CERTIFY ALL FOUR ITEMS)

(1) I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document dated to submit data concerning the active ingredient _____:

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm.")

(2) My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm	Date of Offer

However, none of those firm(s) accepted my offer.

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

Dated: _____ _____
(Signature)

_____
(Typed)

cc: A copy of the offer(s) is attached.

Attachment A

PRODUCTS AFFECTED BY THIS
REREGISTRATION PROCESS

Following is a list of your products affected by this re-registration process. If this list is incomplete or inaccurate in any way, please notify the Product Manager (PM) identified in the letter.

Attachment B

FIFRA § 3(c)(2)(B) SUMMARY SHEET

EPA Registration No.: _____
Product Name: _____
Applicant's Name: _____
Date Guidance Document Issued: _____

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(c)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

1. |___| I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use.

2. |___| I have entered into an agreement with one or more other registrants under FIFRA § 3(c)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by (name of other registrant).

3. |___| I enclose a completed "Statement of Willingness to Enter into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

4. |___| I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

5. |___| I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

Dated: _____

Registrant's authorized representative:

_____
(Signature)

_____
(Typed)

Attachment C

REGISTRANTS WITH PESTICIDE PRODUCTS CONTAINING
THE ACTIVE INGREDIENT ETHION.

The information attached will allow registrants with pesticide products containing the above ingredient to contact one another regarding joint data development or sharing the cost of data development under section 3(c)(2)(B) of FIFRA. This information includes the following: EPA Reg. No., company name, company's address, active ingredient, percentage of active ingredient, and type of formulation, such as Manufacturing-Use-Product (MUP), Technical Product (TP), Wettable Powder (WP), and Emulsifiable Concentrate (EC).

044600-00002 Ethion Technical (94% Ethion MUP)

Tricon Chemicals International Ltd.
Geneva, Switzerland
% Ralph A. Roane
P.O. Box 1103
Clermont, FL 32711

000279-002280 Ethion Technical (95% Ethion MUP)

FMC Corporation
Agricultural Chemical Group
2000 Market Street
Philadelphia, PA 19103

002749-00293 Ethion Technical Insecticide (95% Ethion MUP)

Aceto Agricultural Chemicals Corporation
126-02 Northern Blvd.
Flushing, NY 11368

TABLE D

Labeling Requirements of the FIFRA, as Amended (Refer to the Sample Labels Following)

Item	Label Element	Applicability of Requirement	Placement of Label		Comments
			Required	Preferred	
1	Product Name	All products	Front panel	Center front panel	
2	Company Name and Address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualfied by "Packed for..." "Distributed by..." etc.
3	Net Contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Est. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Reg. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients Statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/Gallon	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.

TABLE E

Item	Label Element	Applicability of Requirement	Placement of Label		Comments
			Required	Preferred	
7A	Keep Out of Reach of Children (Child Hazard Warning)	All products	Front panel	Above Signal Word	Note type size requirements.
7B	Signal Word	All products	Front panel	Immediately below Child Hazard Warning	Note type size requirements.
7C	Skull & crossbones and word "POISON" (in red)	All products which are Category I based on oral, dermal or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		

TABLE F-1

Item	Label Element	Applicability of Requirement	Placement of Label		Comments
			Required	Preferred	
8	Side/back panel Precautionary Statements	All products	None	Top or side of back panel preceding Directions for Use	Must be grouped under the headings in 8A, 8B, and 8C, preferably blocked.
8A	Hazards to Humans and Domestic Animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental Hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.
8C	Physical or Chemical Hazards	All pressurized products, others with flash points under 150°F	None	Same as above	
9A	Restricted Block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9C	Misuse Statement	All products	Immediately following Statement of Classification or ahead of Directions for Use		
10A	Re-entry Statement	All Cholinesterase Inhibitors	In the Directions for Use	Immediately after Misuse Statement	

TABLE F-2

Item	Label Element	Applicability of Requirement	Placement of Label		Comments
			Required	Preferred	
10C	Storage and Disposal block	All products	In the Directions for Use	Immediately before specific directions for use or at the end of Directions for Use	Must be grouped together, and preferably blocked. Heading must be same type size as Child Hazard Warning.
10D U.S.	Directions for Use	All products	None	None	May be in metric units as well as U.S. units.

PROPOSED DISPOSAL STATEMENTS FOR PESTICIDES

PESTICIDE DISPOSAL (all except household)

Pesticide, spray mixture, or rinstate that cannot be used according to label instructions must be disposed of according to Federal, State, or local procedures under the Resource Conservation and Recovery Act.

CONTAINER DISPOSAL

1. Household (all)

Do not reuse empty container (bottle, can, bucket). Wrap (container) and put in trash collection.

2. Metal (all sizes)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by other approved State and local procedures.

3. Plastic (all)

Triple rinse (or equivalent) and offer for recycling or reconditioning, or dispose of in a sanitary landfill, or by incineration if permitted by State and local authorities.

4. Glass (all)

Triple rinse (or equivalent) and dispose of in a sanitary landfill or by other approved State and local procedures.

5. Fiber drums with liners

Dispose of liners according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act. If container cannot be reused*, dispose of in a sanitary landfill or by incineration if permitted by State and local authorities.

*Manufacturer should replace this phrase with one indicating whether and how fiber container may be reused.

6. Paper and plastic bacs

Dispose of bags according to approved Federal, State, or local procedures under the Resource Conservation and Recovery Act.

7. Compressed gas cylinders

Return empty cylinder for reuse (or similar wording).